United States of Federal Claims

No. 90-3409 V (Filed: November 3, 2000)

* * ROBERT LEE TURNER and * SANDRA KAY TURNER, as Legal Representatives on behalf of * ROBERT CLEVELAND TURNER, 42 U.S.C. §§ 300aa-1 et seq. Vaccine Act; factors unrelated; causation. Petitioners, * v. SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, * Respondent. Scott Richard Brann, Houston, TX, for petitioners. Mark William Rogers, Washington, DC, for respondent. **OPINION**

DAMICH, Judge.

Petitioners Robert Lee and Sandra Kay Turner, the parents and legal representatives of Robert Cleveland ("Bobby") Turner, have filed a petition for review of a decision dated May 30, 2000, by the Office of Special Masters denying compensation under the National Childhood Vaccine Injury Compensation Act of 1986, 42 U.S.C. §§ 300aa-1 *et seq.* ("Vaccine Act"). The Special Master found that the Petitioners failed to prove that post-vaccinal symptoms other than seizures were neurologically significant for Petitioners to impeach the Respondent's evidence that tubular sclerosis ("TS") caused in fact the onset of Bobby Turner's seizures. The Petitioners claim that the Special Master, by requiring

them to establish that Bobby's symptoms other than seizures were "neurologically significant," had imposed an evidentiary burden contrary to the Vaccine Act. The Petitioners also allege that the Special Master's findings of fact are not supported by the evidence. For the reasons set forth below, the Court DENIES the Petitioners' motion for review and AFFIRMS the decision of the Special Master.

I. Facts

Bobby Turner suffers from a genetic disease known as tubular sclerosis, ("TS"), that is pre-existent to his vaccination. According to the Respondent's expert, Dr. Robert Zimmerman, Bobby has thirteen cortical tubers. Bobby received his second DPT vaccination on November 21, 1978. Within the evening, Bobby had a fever which responded to symptomatic treatment though the parties dispute the magnitude and duration of the fever. Bobby cried and was irritable that evening, though he also fell asleep and was able to drink without difficulty. Bobby, however, also suffered from significant infantile spasms after the vaccine. The Petitioners claim that all of the symptoms, including the infantile spasms, occurred immediately after his second DPT vaccine.

II. Procedural History

The Petitioners filed a petition for compensation under the Vaccine Act on behalf of Bobby Turner. The original petition alleged that Bobby experienced the first onset of a residual seizure disorder within 3 days after his second DPT vaccination on November 21, 1978. The Petitioners also alleged that the DPT vaccination significantly aggravated his TS condition.

The Special Master who issued the decision in this case was also assigned to over 60 TS-related cases. In the early stages of this litigation, TS children who suffered "on-Table" seizures were entitled to a presumption of significant aggravation of their condition. *Costa v. Sec'y H.H.S.*, 26 Cl. Ct. 866 (1992). On January 22, 1996, the Special Master issued a decision which held that because Bobby's seizures occurred within 3 days of his November 21, 1978 DPT vaccination, his seizures were "on-Table" and therefore presumed to be caused by the vaccine. *Turner v. Sec'y H.H.S.*, No. 90-3489V, slip op. at 6 (Fed. Cl. Sp. Mstr. Jan 22, 1996) ("*Decision* at _____").

However, the Respondent presented new evidence to the Court in all pending TS cases, including Bobby's, concerning the relationship between the cortical tubers of TS patients and their seizures and mental retardation. The evidence suggested that DPT vaccines do not cause seizures in TS patients. The Special Master, therefore, delayed a final decision on entitlement to compensation so that the Respondent could present this evidence. *Decision* at 2.

On April 11, 1996, the Special Master issued an Omnibus Order consolidating all

TS-related vaccine cases, including *Turner*, in order to conduct an expert hearing to determine whether the claimants' seizures and other conditions were due to TS, a "factor unrelated" to the DPT vaccine pursuant to 42 U.S.C. §§ 300aa-13(a)(1)(B). The expert hearing was held from October 8-11, 1996, and June 3-4, 1997.

The Special Master issued a "TS Omnibus Decision" on September 15, 1997. The Special Master found that "TS is the overwhelming cause of seizures in a child afflicted with the disease, unless he develops a fever or some other well-recognized reaction to a vaccination." *Barnes v. Sec'y H.H.S.*, 1997 WL 620115, at * 31 (Fed. Cl. Sp. Mstr. Sept. 15, 1997). Further, the Special Master states "the epidemiology that is available . . . supports the view that DPT does not initiate seizures in TS patients." *Id.* at 32. Consequently, the Special Master determined that,

[r]espondent has successfully rebutted petitioners' presumption of significant aggravation of pre-existing TS from DPT vaccine by proving that TS caused in fact both petitioners onset of seizures and current condition.

Id. at * 34. Hence, in all TS cases, the Special Master found that TS is presumed to have caused all cases of seizures. However, that presumption could be rebutted if ". . . he develops a fever or some other well-recognized reaction to a vaccination." *Id.* at * 31.

Subsequent to the Omnibus decision, the Special Master issued an order granting compensation to the Petitioner. *Turner v. Sec'y H.H.S.*, No. 90-3409V, Order (Fed. Cl. Sp. Mstr. Sept. 27, 1997). Because that order was granted without the benefit of expert testimony, the Special Master ordered the production of medical reports to determine whether the symptoms had neurological significance.

Based on the expert testimony received, on August 18, 1998, the Special Master held that in order for Petitioners to rebut the presumption that TS caused the onset of Bobby's seizures, the Petitioners must show that post-vaccinal symptoms, other than seizures, must exist and be neurologically significant. The Special Master found that Bobby's symptoms did not meet this standard. Bobby's fever was low and his crying and irritability were insufficiently prolonged to have any neurological significance. *Turner v. Sec'y H.H.S.*, No. 90-3409V, 1998 U.S. Claims LEXIS 213, at * 8 (Fed. Cl. Sp. Mstr. August

¹The Special Master's opinion states that ". . . post-vaccinal symptoms, other than seizures, must exist and be neurologically significant for petitioners to rebut the presumption that DPT caused the onset of Bobby's seizures." *Turner v. Sec'y H.H.S.*, No. 90-3409V, 1998 U.S. Claims LEXIS 213, at * 8 (Fed. Cl. Sp. Mstr. August 18, 1998). Given the context of the decision, it is clear that the term "DPT" was a typographical error, and the Special Master meant "TS."

18, 1998). Accordingly, the Special Master dismissed the petition. However, that decision was vacated on September 18, 1998, pending an appeal in *Hanlon v. Sec'y H.H.S.* On May 30, 2000, the day the Supreme Court denied certiorari in *Hanlon*, the Special Master reissued an opinion which reiterated the holding of her August 18, 1998 opinion.² The Special Master dismissed the petition with prejudice. The Petitioners filed a motion for review with the Court on June 21, 2000.

III. Statutory Framework of the Vaccine Act

The Vaccine Act provides a system for compensating individuals who claim to have been injured by certain vaccines. The Vaccine Act essentially shortcuts the burden of proving causation that the petitioner would normally face in standard tort litigation. Instead of proving causation, the Vaccine Act provides a burden-shifting device known as the "Vaccine Injury Table." 42 U.S.C. §§ 300aa-14(a). If a case is "on-Table," then the Table provides a presumption that injuries were caused by the vaccine if the petitioner establishes that the onset or "significant aggravation" of predicate injuries occurred within a time period set by the Table. 42 U.S.C. §§ 300aa-11(c)(1)(C)(i).

However, the respondent has the opportunity to rebut this presumption. If the respondent proves that the injuries sustained were due to "factors unrelated" to the vaccine, the petitioner cannot be compensated. 42 U.S.C. §§ 300aa-13(a)(1)(B).³ If the government claims that the injuries were due to a "factor unrelated," the petitioner can respond to the "factor unrelated" claim by stating that the alleged factor was not "principally responsible" for the injury suffered. Thus, the special master shall, in determining whether to award compensation to the petitioner, weigh the proffered evidence provided by both petitioner and respondent including all "relevant medical and scientific evidence contained in the record" as well as "any . . . diagnosis, conclusion, [or] medical judgment . . . regarding the nature, causation, and aggravation of the petitioner's illness 42 U.S.C. §§ 300aa-13(b)(1).

IV. Standard of Review

² "[T]he Court finds that post-vaccinal symptoms, other than seizures, must exist and be neurologically significant for petitioners to impeach respondent's evidence that TS caused in fact the onset of Bobby's seizures. Bobby's symptoms did not have neurological significance." *Turner v. Sec'y H.H.S.*, No. 90-3409V, 2000 U.S. Claims LEXIS 113, at * 9 (Fed. Cl. Sp. Mstr. May 30, 2000) ("Final Decision").

³ The statute provides that "factors unrelated" may include those injuries such as "trauma . . . which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death." 42 U.S.C. §§ 300aa-13(a)(2)(B).

The Court must uphold any findings of fact or conclusions of law of the Special Master unless the findings are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. §§ 300aa-12(e)(2)(B). With respect to findings of fact, the Special Master has broad discretion to weigh expert evidence and make factual determinations. *Bradley v. Sec'y H.H.S.*, 991 F.2d 1570, 1575 (Fed. Cir. 1986). "If the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Hines v. Sec'y H.H.S.*, 970 F.2d 863 (Fed. Cir. 1992).

V. The Special Master Properly Allocated The Burdens Of Proof In Accordance With The Vaccine Act

The Petitioners claim that the Special Master improperly required them to establish that Bobby's symptoms of fever, crying, irritability, and so on had "neurological significance" apart from TS. (Pl.'s Mot. at 5.) The Petitioners note that the term "neurological significance" does not appear anywhere in the statute or the TS Omnibus Decision. *Id.* They further claim that having to prove that Bobby's symptoms were "neurologically significant" would defeat the statutory presumption of entitlement to compensation for "on-Table" DPT cases. *Id.* at 7. The Petitioners further contend that establishing the "neurological significance" of the symptoms would serve as an impossible burden on the Petitioners, and that the Respondent did not fully prove that Bobby's symptoms were "factors unrelated" to the vaccine. *Id.* at 7-8.

The Respondents argue that the Federal Circuit in *Hanlon* had already determined conclusively that TS is a factor unrelated in any case where the Table onset of symptoms constituted *seizures only*, and that the Special Master only had to determine whether the other symptoms were of such importance so as to warrant a departure from the findings of the Omnibus opinion. (Def's Resp. at 15). As to the allocation of evidentiary burdens, the Respondent characterizes the demonstration of "neurological significance" as "one final opportunity to rebut respondent's convincing proof that the child's TS is the cause of his condition." *Id.* at 16. The Respondent claims that this allocation of evidentiary burdens was fully approved by the Federal Circuit in *Hanlon*.

The Federal Circuit's decision in *Hanlon* does not explicitly mention or affirm any "one final opportunity to rebut" the respondent's evidence that TS causes DPT. However, the prior Court of Federal Claims decision in *Hanlon* does affirm an allocation of evidentiary burdens that is similar to the present case. Before the Court of Federal Claims, the petitioners argued that the Special Master held them to a causation-in-fact standard after they had satisfied their "on-Table" presumption. *Hanlon v. Sec'y H.H.S.*, 40 Fed. Cl. 625, 631. Judge Turner answered this objection by stating that the "[r]espondent simply put on a strong rebuttal which itself "required" petitioners to do more than rest on their prima facie showing if they wished to prevail. We conclude that petitioners were not

required to prove that DPT caused in fact [petitioner's] seizures in order to prove a Table injury." *Id.* The Respondent, therefore, infers that the affirmation by the Federal Circuit serves as an affirmation of the Special Master's evidentiary standard. Since the Federal Circuit did not squarely address that issue, such an inference is not necessarily true. The best inference that can be drawn from the Federal Circuit's decision in *Hanlon* is that providing the petitioner with "one final opportunity to rebut" the respondent's presumption that TS, not DPT, vaccines caused Bobby's symptoms is not necessarily inconsistent with the evidentiary burdens established by the Vaccine Act. Therefore *Hanlon* is not controlling in this case.

Nevertheless, requiring the Petitioners to demonstrate "neurological significance" to rebut the Respondent's proof that TS was the cause of Bobby's symptoms is neither unreasonable nor contrary to the Vaccine Act. The fact that the Special Master initially decided in favor of entitlement to compensation on January 22, 1996, and issued an order to that effect on September 27, 1997, demonstrates that the Petitioners had in fact already met their on-Table evidentiary presumption and that the Respondent had not yet, by a preponderance of the evidence, proved that Bobby's symptoms were caused by TS. The Special Master never imposed a burden on the Petitioners of proving causation-in-fact. Not until expert reports were taken on neurological impairment, did the Respondent prove that Bobby's post-vaccinal symptoms were caused by TS rather than the vaccine.⁴ In no sense can it be said that the Court imposed an extra evidentiary burden not contemplated by the Vaccine Act. Instead, the Special Master gave the Petitioners an extra opportunity to rebut the Omnibus Decision that TS did not cause Bobby's fussiness, crying, and fever.

Likewise, the requirement to demonstrate "neurological significance" to rebut the respondent's presumption that TS caused Bobby's symptoms is not an impossible burden. It is understood that the term "significance" suggests that the evidence provided need not be conclusive, but only evidence that is not unimportant. This burden was not a difficult standard for the petitioners to meet. In fact, the petitioners did not meet this standard at all by failing to interpret Bobby's seizures. *Final Decision* at 8.

It is understandable that the Petitioners would be disappointed by their sudden reversal of fortune after the Special Master decided to reconsider her decision and to take expert testimony. Nevertheless, that decision was well within the scope of her discretion to consider "relevant medical and scientific evidence." 42 U.S.C. §§ 300aa-12(a)(1). The Court has no reason to second-guess her in this regard.

⁴ The Special Master in her final decision noted that the Petitioners' expert, Dr. Kinsborne completely failed to interpret Bobby's symptoms at all, but instead tried to relitigate the Omnibus Decision that TS, not DPT, causes seizures, while in contrast the Respondent's experts clearly analyzed symptomatology. *Final Decision* at 8. Under such circumstances, the Respondent satisfied its prima facie case outright.

VI. The Special Master Did Not Abuse Her Discretion In Finding That TS Was The Cause of Petitioner's Symptoms

The Petitioners argue that the Special Master erred by failing to follow her own prior rulings in TS related cases. Specifically, the Petitioners seize on the following statement by the Special Master in the TS Omnibus Decision: "where a TS child receives DPT vaccine, and remains perfectly normal, in temperature, eating, sleeping, affect, and activity, but has a seizure within three days, TS, not DPT is the cause of that seizure." *Barnes*, 1997 WL 620115 at * 32. Because Bobby Turner displayed a majority of those symptoms, so the Petitioners argue, the Special Master was required to find that DPT, rather than TS, significantly aggravated Bobby's seizures. However, the Court cannot agree with such a simplistic "checklist" approach to determining whether Bobby's non-seizure symptoms were significantly aggravated by his vaccine. Such an analysis does not take into account the duration or magnitude of Bobby's non-seizure symptoms. Nor does such an approach even attempt to find a medical nexus between Bobby's symptoms and the vaccine. A medical judgment in which Bobby's various symptoms are analyzed qualitatively by experts, as the Special Master provided for, is reasonable.

The record clearly shows that the Special Master reviewed the evidence submitted by the experts. The Special Master clearly relied on the opinion of the Respondent's expert, Dr. Guggenheim, that

"... Bobby's infantile spasms were related to his underlying TS because he did not have an acute encephalopathy after his DPT vaccination ... The fever that he had on the evening of the vaccination lasted only a few hours and responded to symptomatic treatment ... Although Bobby cried and was fussy, irritable, and whiny, he fell asleep and was able to drink without difficulty. The seizures were his only neurologic abnormality."

Final Decision at * 1. In contrast, the Special Master found that the Petitioners' expert,

Dr. Kinsbourne, "failed to interpret Bobby's symptoms," and instead focused on "rearguments of the issues the undersigned had already decided in the TS Omnibus Decision." *Final Decision* at * 9-10. These findings by the Special Master are entitled to deference. The Court holds that the Special Master made reasonable inferences in

⁵ The Petitioners also re-argue factual issues that were before the Special Master in the Omnibus TS Decision and ultimately affirmed on appeal; namely, the ongoing relationship between TS and DPT vaccines and the merits of the position of experts who testified in that proceeding. (Pet.'s Mot. at 13-17). Such arguments are not properly before the Court and therefore will not be considered.

weighing the medical evidence on the record and, therefore, her inferences shall remain unmolested.

VII. Conclusion

Therefore, the Court AFFIRMS the Special Master's decision dated May 30, 2000. The petition is dismissed with prejudice.

EDWARD J. DAMICH Judge